



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Su Chen

Title:

**OXYGEN-18 LABELED** 

ORGANIC ACIDS AND USE IN DIAGNOSING METABOLIC

**DISORDERS** 

Appl. No.:

10/696,051

Filing Date:

10/28/2003

Examiner:

Unassigned

Art Unit:

1651

# CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below. DIAME GARCIA (Printed Name) (Signature) SHUGHA (Date of Deposit)

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment (IDS) Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

# TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

# RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date

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Substitute for form 1449B/PTO	Complete if Known			
Alle INFORMATION DISCLOSURE	Application Number	10/696,051		
AUG O SEATEMENT BY APPLICANT	Filing Date	10/28/2003		
**************************************	First Named Inventor	Su Chen		
	Group Art Unit	1651		
TRADEMISSOR as many sheets as necessary)	Examiner Name	Unassigned		
Sheet 1 of 3	Attorney Docket Number	034827-2601		

	U.S. PATENT DOCUMENTS							
Examiner Initials*	0:1	U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant		
	Cite No. <sup>1</sup>	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear		

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Examiner Initials*	Cite No. <sup>1</sup>	Fore Office <sup>3</sup>	eign Patent D Number <sup>4</sup>	Occument Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	,T <sup>6</sup>
	A1	CHEN and CARVEY, "Validation of Liquid-Liquid Extraction Followed by Flow-Injection Negative Ion Electrospray Mass Spectrometry Assay to Topiramate in Human Plasma," <i>Rapid Commun Mass Spectrom</i> , 15:159-163 (2001)	
	A2	CLAY and MURPHY, "New Procedure for Isolation of Amino Acids Based on Selective Hydrolysis of Trimethylsilyl Derivatives," <i>Journal of Chromatography</i> , 164: 417-426 (1979)	
	А3	GLEISPACH, et al., "Neuroblastoma Screening: Labeling of HVA and VMA for Stable Isotope Dilution Gas Chromatography-Mass Spectrometry," Supplement to <i>Nutrition</i> , 11: 604-606 (1995)	
•	A4	HEALES and LEONARD, "Diagnosis of Medium Chain Acyl CoA Dehydrogenase Deficiency by Measurement of cis-4-Decenoic Acid in Dried Blood Spots," Clinica Chimica Acta, 209: 61-66 (1992)	
	A5	IKEGAWA et al., "Separation and Detection of Bile Acid 24-Glucuronides in Human Urine by Liquid Chromatography Combined With Electrospray Ionization Mass Spectrometry." Analytical Sciences, 15: 625-631 (1999)	
,	A6	JAKOBS and de GRAUW, "A Fatal Case of 2-Keto-, 2-Hydroxy- and 2-Aminoadipic Aciduria: Relation of Organic Aciduria to Phenotype?" <i>Inher. Metab. Dis.</i> 15: 279-280 (1992)	

Examiner Signature	Date Considered	

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	Substitute for f	orm 1449B	/PTO		Complete if Known	
	INFORMATION	N DISCLO	SURE	Application Number	10/696,051	
	STATEMENT I	BY APPLI	CANT	Filing Date	10/28/2003	
				First Named Inventor	Su Chen	
				Group Art Unit	1651	
(use as many sheets as necessary)				Examiner Name	Unassigned	
Sheet	2	of	3	Attorney Docket Number	034827-2601	

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>				
A7		JORG LEIS et al., "Synthesis of [1802] Valproic Acid and Its Use as an Internal Standard For the Quantitative Measurement by Gas Chromatography-Electron Ionization Mass Spectrometry," Journal of Chromatography B, 784: 69-75 (2003)					
	A8	KUSHNIR et al., "Analysis of Dicarboxylic Acids by Tandem Mass Spectrometry. High-Throughout Quantitative Measurement of Methylmalonic Acid in Serum, Plasma and Urine." Clin Chem 47(11): 1993-2002 (2001)					
	A9	LIEBICH and FÖRST, "Hydroxycarboxylic and Oxocarboxylic Acids in Urine: Products From Branched-Chain Amino Acid Degradation and From Ketogenesis," <i>Journal of Chromatography</i> , 309: 225-242 (1984)					
	A10	MAGERA et al., "Determination of Homovanillic Acid in Urine by Stable Isotope Dilution and Electrospray Tandem Mass Spectrometry," Clinica Chimica Acta, 306: 35-41 (2001)					
	A11	MIRGORODSKAYA et al., "Quantitation of Peptides and Proteins by Matrix-Assisted Laser Desorption/lonization Mass Spectrometry Using <sup>18</sup> O-Labeled Internal Standards," Rapid Commun. Mass. Spectrom., 14: 1226-1232 (2000)					
	A12	MURPHY and CLAY, "Synthesis and Back Exchange of <sup>18</sup> O Labeled Amino Acids For Use as Internal Standards With Mass Spectrometry." <i>Biomedical Mass Spectrometry</i> , Vol. 6, No. 7: 309-314 (1979)					
	A13	PITT et al., "Comprehensive Screening of Urine Samples For Inborn Errors of Metabolism by Electospray Tandem Mass Spectrometry," Clin Chem 48(11): 1970-1980 (2002)					
	A14	SHIGEMATSU et al., "A Simple Method of Determining 4-Hydroxyisovaleric Acid and Its Level in a Patient with Isovaleric Acidemia," Clinica Chimica Acta, 138: 333-336 (1984)					
	A15	SWEETMAN, "Organic Acid Analysis," In (Hommes, Ed.) Techniques in diagnostic human biochemical genetics Wiley-Liss: New York, 143-176 (1991)					
	A16	TRUSCOTT et al., "The Identification of 3-Keto-2-Methylvaleric Acid and 3-Hydroxy-2-Methylvaleric Acid in a Patient With Propionic Acidemia," Biomedical Mass Spectrometry, 6: 294-300 (1979)					
	A17	TSERNG et al., "Urinary 3-Hydroxyadipic Acid 3,6-Lactone: Structural Identification and Effect of Fasting in Adults and Children," Metabolism, 38: 655-661 (1989)					
	A18	VAN ROOYEN <i>et al.</i> , "Identification of the Steroisomeric Configurations of Methylcitric Acid Produced by <i>si</i> -Citrate Synthase and Methylcitrate Synthase Using Capillary Gas Chromatograpy-Mass Spectrometry," <i>J. Inher. Metab. Dis.</i> , 17: 738-747 (1994)					
	A19	VELDINK et al., "Oxygen Transfer in the Enzymatic Conversion of <sup>18</sup> 0-Labelled Linoleic Acid Hydroperoxide into the 12-Keto-13-Hydroxy-Octadec-C/S-9-Enoic Acid," FEBS Letters, 7: 188-190 (1970)					

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	A20	YOUHNOVSKI, et al., "Determination of Hydroxyoctadecadienoic Acids," Z. Naturforsch, 58c: 268-279 (2003)				
	A21	ZYTKOVICZ et al., "Tandem Mass Spectrometric Analysis for Amino, Organic, and Fatty Acid Disorders in Newborn Dried Blood Spots: A Two-Year Summary From the New England Newborn Screening Program." Clin Chem 47(11): 1945-1955 (2001)				

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